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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/303,510 | 04/30/99 | COLLISSON | E 54954/JPW/TV |

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| EXAMINER | |
|---|---|
| WINKLER,U | |
| **ART UNIT** | **PAPER NUMBER** |
| 1648 | 13 |

**DATE MAILED:** 01/02/01

**Please find below and/or attached an Office communication concerning this application or pr ceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/303,510 | COLLISSON ET AL. | |
| | Examiner | Art Unit | |
| | Ulrike Winkler, Ph.D. | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 October 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2,6,48-52,55,56,62-64,83-85,89 and 90* is/are pending in the application.

4a) Of the above claim(s) *61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,6,48-52,55,56,62-64,83-85,89 and 90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## DETAILED ACTION

The Amendment filed 2 October 2000 (Paper No. 12) in response to the Office Action of 29 March 2000 is acknowledged and has been entered. Claims 46, 47 and 86-88 have been cancelled, claim 2 has been amended and claims 89 and 90 have been added. Claims 2, 6, 48-52, 55, 56, 62-64, 83-85, 89 and 90 are pending and are currently being examined. Claim 61 is withdrawn, claim 61 is drawn to a non-elected species pertaining solely to CD80 and is not directed to a fusion protein with elected species CD86 such as the CD86/CD80 fusion protein; in addition claim 61 is dependent on a canceled claim 53.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The office acknowledges the receipt of the substitute specification, which incorporates all the previous amendments.

The rejection of claims 2, 83 and newly added claims 89 and 90 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained** for reasons of record. Applicant's arguments filed 2 October 2000 have been fully considered but they are not persuasive. Applicant contends that the specification provides primers that would allow the ordinary artisan to sequence the genomic DNA. This is a written description rejection; having the tools to be able to be able to determine the genomic DNA does not equate to being in possession of the genomic

DNA sequences at the time of filing. Changing the wording to "an isolated nucleic acid consisting essentially of SEQ ID NO: 5" would obviate this rejection.

The rejection of claims 2, 87 and 88 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** due to cancellation of claims 87 and 88.

The rejection of claims 2, 55 and 86 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** due to Applicant's arguments.

The rejection of claims 2, 46, 47, and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** due to cancellation of the claims containing the phrase "genomic DNA".

The rejection of claims 2, 87 and 88 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** due to cancellation of claims 87 and 88.

The rejection of claims 2, 55 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** due to Applicant's arguments.

The rejection of claims 2, 6, 46, 48- 52, 55, 56, 62-64, and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (U.S Pat. No. 5,942,607) **is maintained** in light of Applicant's amendment to claim 2. Applicant's arguments filed 2 October 2000 have been fully considered but they are not persuasive. Applicant's amendment to claim 2 "wherein the isolated nucleic acid is at least about 70% homologous" does not obviate the rejection; in fact, the nucleic acid sequence disclosed by Freeman et al. is at least about 70% to the sequence of the instant specification. Therefore, the rejection is maintained.

The rejection of claims 2, 55 and 86-87 under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (U.S Pat. No. 5,942,607) and Hash (Gene Bank Direct Submission, 8 May 1996) **is withdrawn** due to cancellation of claims 86 and 87.

New Grounds of Rejection Necessitated by Applicant's Amendments:

Claim 2 and dependent claims 6, 83, 48-52, 55, 56, 62, 63, 64 and 83-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification, while being enabling for SEQ ID NO: 5 coding for the polypeptide of SEQ ID NO: 6, does not reasonably

provide enablement for the other homologous sequences or polynucleotide sequences comprising the SEQ ID NO:5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification discloses the identification and characterization of a feline CD86 protein with SEQ ID NO: 6 and the corresponding nucleic acid sequence of SEQ ID NO:5. It would be undue burden for one of skill in the art to practice the claimed invention in terms of making all the homologous sequences from the disclosed sequences, because the specification provides no guidance as to the many different homologous sequences that can be produced. A 70% homology of SEQ ID NO:5 corresponds to a nucleotide difference of 324 nucleotides. This nucleotide change could conceivably be a change in 324 amino acids, which equates to a potential similarity of only 10% at the amino acid level. These nucleotide substitutions can be arranged contiguously or sparsely at different positions on a sequence. The state of the art is such that it can not predict what substitution will result in significant structural or functional changes. The classic example of structural/functional differences is hemoglobin where a single amino acid substitution due to a single nucleotide change has significant consequences on the ability of the mutant hemoglobin to carry oxygen. A second example comes from a bacterial protease (Riffkin et al. Gene Vol. 167, 1995, pp 279-283), where a change in two nucleotides of the protease sequence results in the difference between virulent and benign infection. This small difference not only results in epitope differences but also results in changes to the thermostability, elastolytic and caseinolytic activity of the protease. There is no guidance in the specification to teach where the sequence should be substituted, and therefore, the functionality

of the protein would be unpredictable. Moreover, one of skill in the art would not know which position of the substitution would retain the characteristics of CD86 without undergoing extensive experimentation. Therefore, the instant specification does not provide enablement commensurate with the scope of the claims.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specification does not provide any indication as to what range of homology is covered by the term "about". Therefore, the phrase "at least about 70% homologous" is indefinite.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 and all the dependent claims 6, 48-42, 55, 56, 62-64, 83-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman et al. (WO9503408).

The instant invention is directed to the nucleic and amino acid sequence of feline CD86, oligonucleotide probes and vectors encoding the nucleic acid sequence of feline CD86.

Freeman et al. teach the human B7-2 (CD86) nucleic acid and amino acid sequence (see fig 8). Freeman et al. also teach inserting the CD86 nucleic acid sequence into an expression vector and inserting the vector into a cell such as a COS cell for expression. Freeman et al.

provides motivation and an expectation of success for determining members of CD86 in various species. The reference also provides oligonucleotides useful as diagnostic tools when labeled with a detectable marker. Freeman et al. discloses the nucleotide sequence that is at least about 70% homologous to the instant sequence. Therefore, the instant invention is anticipated by Freeman et al.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Azuma et al. (WO9506738).

The instant invention is directed to the nucleic and amino acid sequence of feline CD86.

Azuma et al. disclose a nucleotide sequence SEQ ID NO: 1 that is at least about 70% homologous to the instant sequence. Therefore, the instant invention is anticipated by Azuma et al.

Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent specific plasmid vector is required to practice the claimed invention. As such it must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by an enabling deposit of the vector. It is noted that the Applicants have deposited the plasmid vector B7-2#19-2/011298

(ATCC No. 209821) but there is no indication in the specification as to public availability. Therefore, a statement regarding the public availability may be made for enablement purposes.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years. Or 5 years after the last request for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

## *Conclusion*

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

JEFFREY STUCKER
PRIMARY EXAMINER